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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ANDERSON, JAMES D	

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1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/780,797	MUNN ET AL.	
	Examiner	Art Unit	
	JAMES D. ANDERSON	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-7,10,12,13,30-39 and 44-69* is/are pending in the application.

4a) Of the above claim(s) *5-7,10,12 and 35-39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,13,30-34 and 44-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :7/9/2008, 11/3/2008, and 11/12/2008.

DETAILED ACTION

Formal Matters

Applicants' response and amendments to the claims, filed 10/14/2008, are acknowledged and entered. Claims 9 and 11 have been cancelled by Applicant. Claims 44-69 are newly added. Claims 1, 2, 4-7, 10, 12, 13, 30-39, and 44-69 are pending.

Claims 5-7, 10, 12, and 35-39 remain withdrawn from further consideration in light of the Restriction Requirement mailed 12/20/2006 and Applicant's elections filed 1/19/2007.

Accordingly, claims 1, 2, 4, 13, 30-34, and 44-69 are presently under examination and are the subject of this Office Action.

Election/Restrictions

The Election of Species requirement set forth in the Requirement for Restriction/Election at pages 6-7 is withdrawn in part. Specifically, the requirement to elect a specific species of therapeutic agent from the elected sub-genus (chemotherapeutic agents) is hereby **withdrawn**. Accordingly, search and examination is extended to the claimed methods comprising 1-methyl-D-tryptophan in combination with other chemotherapeutic agents.

Applicant's amendments to the claims necessitated the withdrawal of the above election of species requirement.

Response to Arguments

Any previous rejections and/or objections to claims 9 and 11 are **withdrawn** as being moot in light of Applicant's cancellation of the claims.

Information Disclosure Statement

Receipt is acknowledged of the Information Disclosure Statements filed 7/9/2008, 11/3/2008, and 11/12/2008. The Examiner has considered the references cited therein to the extent that each is a proper citation. Please see the attached USPTO Form 1449.

Declaration under Rule 1.132

The Examiner acknowledges receipt of the Rule 1.132 Declaration of George C. Prendergast ("Prendergast" Declaration) and has carefully considered the information provided therein. The purpose of the Declaration, as stated by the Declarant, is to provide factual evidence that 1-D-methyl-tryptophan (D-1MT) can be effective in inhibiting multiple cancer types. In support of this declaration, Exhibits A and B are presented, which graph the anti-cancer effects of the administration of D-1MT in conjunction with a chemotherapeutic agent (cyclophosphamide) against lung cancer and colon cancer, respectively.

With respect to the treatment of lung cancer (Exhibit A) and colon cancer (Exhibit B), the antitumor effects of the combined therapy clearly demonstrate an unexpected synergistic effect that would not be predicted based upon the effect of either D-1MT or cyclophosphamide alone.

Claim Rejections - 35 USC § 112 – 1st Paragraph – New Grounds of Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4, 13, 30-34, 44-45, 49-50, and 54-68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a written description rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1st "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The instant claims have been amended to recite administration of an effective amount of *a pharmaceutical composition consisting essentially of 1-methyl-D-tryptophan*, and administering at least one additional therapeutic agent (claims 1 and 32-34). Newly added

claims recite administration of a pharmaceutical composition *consisting essentially of* 1-methyl-D-tryptophan (e.g., claims 44 and 49). No support is found in the originally filed disclosure for the recited administration of compositions consisting essentially of 1-methyl-D-tryptophan. Accordingly, the amended and newly added claims introduce new matter into the claims.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, states that Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the written description inquiry, is whatever is now claimed (see page 1117).

Lack of Ipsis Verbis Support

The present application is void of support for the newly claimed administration of pharmaceutical compositions *consisting essentially of* 1-methyl-D-tryptophan or administration of *a pharmaceutical composition consisting essentially of 1-methyl-D-tryptophan* and administering at least one additional therapeutic agent. The instant specification discloses methods of treating cancer and tumors comprising administering an inhibitor of indoleamine-2,3-dioxygenase and administering at least one antineoplastic chemotherapeutic agent (page 2, lines 12-17; page 3, lines 28-30; page 4, lines 3-5; page 4, lines 9-11). Applicants also state improved efficacy of therapeutic outcome with the administration of an inhibitor of indoleaminde-2,3-dioxygenase in combination with an additional therapeutic agent (page 13, lines 29-31). In accordance with the invention, "an IDO inhibitor is administered to a subject in combination with the administration of one or more previously known treatment modalities (page 15, lines 9-10). Nowhere do Applicants disclose compositions *consisting essentially of* 1-methyl-D-tryptophan nor do Applicants disclose what is or is not an essential component of such compositions.

Lack of Implicit or Inherent Support

Section 2163 of the MPEP states: "While there is no *in haec verba* requirement, newly added claim limitation must be supported in the specification through express, implicit, or inherent disclosure".

The instant specification discloses that the administration of the IDO inhibitor may take place before, during, or after the administration of the other mode of therapy (page 16, lines 20-21) and that inhibitors of IDO may be formulated as a composition (id. at line 22). Applicants

further disclose that the compositions may include one or more accessory agents including diluents, buffers, binders, disintegrants, surface active agents, thickeners, lubricants, preservatives, (including antioxidants), and the like (page 16, line 29 to page 17, line 2). The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). Applicants do not disclose which of these accessory agents do or do not materially affect the basic and novel characteristic(s) of the claimed invention. Applicants also disclose that formulations of an IDO inhibitor may further include one or more additional therapeutic agents (page 17, lines 3-4).

As such, one would not conclude that the instant specification provides adequate support for the claimed pharmaceutical compositions *consisting essentially of* 1-methyl-D-tryptophan.

Claims 1-2, 4, 13, 30-34, and 44-69 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating cancer, augmenting the rejection of tumor cells, or reducing tumor size or slowing tumor growth comprising administering 1-methyl-D-tryptophan and cyclophosphamide, wherein the administering of 1-methyl-D-tryptophan and cyclophosphamide demonstrates therapeutic synergy or provides a greater effect than that obtained by administering either agent alone, does not reasonably provide enablement for 1) treating cancer, augmenting the rejection of tumor cells, or reducing tumor size or slowing tumor growth comprising administering 1-methyl-D-tryptophan and other chemotherapeutic agents, wherein the administering of 1-methyl-D-tryptophan and the other chemotherapeutic agent demonstrates therapeutic synergy or provides a greater effect than that obtained by administering either agent alone (claims 1-2, 4, 13, 30-34, 45, 48, 50, 53-54, and 68-69), or 2) treating cancer or reducing tumor size or slowing tumor growth comprising administering 1-methyl-D-tryptophan alone (claims 44, 46-47, 49, 51-52, and 55-67). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. This is a Scope of Enablement rejection.

To be enabling, the specification of the patent application must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.

In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated that:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).[1]

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 wherein, citing *Ex parte Forman*, 230 USPQ 546 (Bd. Apls. 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,
7) the predictability of the art, and
8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. *In re Fisher*, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the *Wands* factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention, state and predictability of the art, and relative skill of those in the art

The invention relates to the treatment of cancer, augmenting the rejection of tumor cells, or reducing tumor size or slowing tumor growth comprising administering 1-methyl-D-

[1] As pointed out by the court in *In re Angstadt*, 537 F.2d 498 at 504 (CCPA 1976), the key word is "undue", not "experimentation".

tryptophan alone or in combination with chemotherapeutic agents. The relative skill of those in the art is high, generally that of an M.D. or Ph.D. The artisan using Applicant's invention would generally be a physician with a M.D. degree and several years of experience.

That factor is outweighed, however, by the unpredictable nature of the art. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved", and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 166 USPQ 18, at 24 (In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.), *Nationwide Chemical Corporation, et al. v. Wright, et al.*, 192 USPQ 95 (one skilled in chemical and biological arts cannot always reasonably predict how different chemical compounds and elements might behave under varying circumstances), *Ex parte Sudilovsky* 21 USPQ2d 1702 (Appellant's invention concerns pharmaceutical activity. Because there is no evidence of record of analogous activity for similar compounds, the art is relatively unpredictable) *In re Wright* 27 USPQ2d 1510 (the physiological activity of RNA viruses was sufficiently unpredictable that success in developing specific avian recombinant virus vaccine was uncertain).As illustrative of the state of the art, the examiner cites Sausville *et al.* (Cancer Research, 2006, vol. 66, pages 3351-3354) and Johnson *et al.* (British J. of Cancer, 2001, 84(10):1424-1431).

Sausville *et al.*, cited for evidentiary purposes, teaches that traditionally explored tumor model systems are insufficient to predict how actual human beings will respond to treatment in the clinic (page 3351, left column). Even when drugs with evidence of anticancer activity in preclinical *in vivo* models are given their maximum tolerated dose in humans, they frequently fail to produce useful activity in humans (*id.*). Also, with regard to unpredictability, Johnson *et al.*, also cited for evidentiary purposes, teach that the *in vivo* activity of 39 different agents in a particular histology in a tumor model did not correlate to activity in the same human cancer. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Further, the mode of action of anticancer agents is often unknown or very unpredictable and administration of such agents is often accompanied by undesirable side effects.

These articles plainly demonstrate that the art of treating cancer, particularly in humans, is extremely unpredictable, particularly in the case of a single compound being used to treat any and all cancers.

2. The breadth of the claims

The claims are extremely broad insofar as they disclose the general treatment of cancer and tumors with the same compound, both alone and in combination with any chemotherapeutic agent. The claims further require that when administered in combination, 1-methyl-D-tryptophan and the chemotherapeutic agent not only treat cancer or tumors, but demonstrate "therapeutic synergy".

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction or guidance for determining the particular administration regimens (*e.g.*, dosages, timing, administration routes, etc.) necessary to provide a synergistic effect in cancers and/or tumors, particularly in humans. The direction concerning treating cancer and tumors is found in the specification at pages 13-20, which provides no guidance with respect to determining the amounts of 1-methyl-D-tryptophan and additional chemotherapeutic agent required to provide a synergistic effect. Since only one combination as instantly claimed has ever been used to treat any human cancer, how is the skilled physician to know what doses to use for each of these pathologically different cancers and structurally and mechanistically diverse chemotherapeutic agents? There is an *in vivo* assay described in pages 48-49, which demonstrates the therapeutic synergy of 1-methyl-D-tryptophan and cyclophosphamide in melanoma tumors. The Prendergast Declaration demonstrates that such synergism is also observed in colon and lung tumors. However, it is unclear if these results correlate to or are predictive of therapeutic synergy in all of the cancers encompassed by the claims by all of the combinations encompassed by the claims. For example, there is no a single example of a chemotherapeutic agent other than cyclophosphamide demonstrating therapeutic synergy when administered with 1-methyl-D-tryptophan.

Further, with respect to claims 44, 46-47, 49, 51-52, and 55-67, Applicant's results from in vivo testing demonstrate that 1-methyl-DL-tryptophan and 1-methyl-D-tryptophan are ineffective in inhibiting melanoma tumor growth when administered as single agents (Figure 11D). The Prendergast Declaration demonstrates that 1-methyl-D-tryptophan is also ineffective at inhibiting colon or lung tumor growth when administered as a single agent (Exhibits A and B). As such, Applicant's own work casts significant doubt on the ability of 1-methyl-D-tryptophan administered as a single agent to treat cancer or tumors as recited in the newly added claims.

4. The quantity of experimentation necessary

Because of the known unpredictability of the art (as discussed *supra*) and in the absence of experimental evidence commensurate in scope with the claims, the skilled artisan would not accept the assertion that 1-methyl-D-tryptophan alone, or in combination with the plethora of structurally and mechanistically diverse chemotherapeutic agents encompassed by the claims could be predictably used as a treatment for all cancers or tumors, wherein the combined therapy demonstrates therapeutic synergy, as inferred in the claims and contemplated by the specification.

Genentech Inc. vs. Nova Nordisk states, "[A] patent is not a hunting license. It is not a reward for a search but a compensation for its successful conclusion and 'patent protection' is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" (42 USPQ 2d 1001, Fed. Circuit 1997).
In the instant case, Applicants have presented a general idea that because 1-methyl-D-tryptophan in combination with cyclophosphamide demonstrates therapeutic synergy in the treatment of melanoma tumors, then 1-methyl-D-tryptophan alone or in combination with other chemotherapeutic agents must therefore, *a priori*, be useful in the treatment of cancers and tumors. However, the claims encompass a multitude of cancers having distinct pathologies and a multitude of possible drug combinations

Applicants tested one such combination for inhibition of melanoma tumor growth. Determining if any particular claimed cancer or tumor could be treated with 1–methyl-D-tryptophan would require subjecting it to clinical trials or to testing in an assay known to correlate to clinical efficacy of such treatment. In light of Applicant's own results, one skilled in

the art would not expect 1-methyl-D-tryptophan to be an effective antitumor agent when administered alone. With respect to combination therapy, it would require an extensive amount of hit-or-miss testing to determine what other chemotherapeutic agents, in what amounts, might exhibit the therapeutic synergy demonstrated by 1-methyl-D-tryptophan and cyclophosphamide. This is undue experimentation given the limited guidance and direction provided by Applicants. As noted *supra*, even *in vitro* and *in vivo* assays do not always correlate to efficacy in humans and are not generally predictive of clinical efficacy.

Accordingly, the instant claims do not comply with the enablement requirement of 35 U.S.C. § 112, first paragraph, since to practice the claimed invention a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of claims 1-2, 4, 9, 11, 13, and 32-34 under 35 U.S.C. 102(e) as being anticipated by Prendergast *et al.* (WO 2004/093871 A1; Published November 4, 2004), is **withdrawn** in light of Applicants' amendments. Prendergast et al. do not teach administration of pharmaceutical compositions consisting essentially of 1-methyl-D-tryptophan.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 30 and 31 under 35 U.S.C. 103(a) as being obvious over **Prendergast *et al.*** (WO 2004/093871 A1; Published November 4, 2004) is **withdrawn** in light of Applicant's amendments and arguments.

Firstly, Applicants have amended the claims to recite administration of 1-methyl-D-tryptophan. Prendergast et al. teach administration of the racemic mixture of 1-methyl-DL-tryptophan and do not provide an explicit or inherent teaching or suggestion to administer the individual isomers. Secondly, even if it could be argued that the individual isomers are obvious over Prendergast et al., the prior art teaches that 1-methyl-*L*-tryptophan is the substantially more potent inhibitor of indoleamine-2,3-dioxygenase (see Peterson et al. (Med. Chem. Res., 1994, vol., 3, pages 531-534). As such, the prior art teaches away from selecting 1-methyl-D-tryptophan for use as an inhibitor of indoleamine-2,3-dioxygenase in the cancer treatment methods disclosed in Prendergast et al. Applicants have unexpectedly found that 1-methyl-D-tryptophan is more effective than the L isomer at reversing IDO-mediated suppression and more effective than the racemic mixture is delaying tumor growth.

The rejection of claims 1-2, 4, 9, 11, 13, and 30-34 under 35 U.S.C. 103(a) as being unpatentable over **WO 00/66764** and **Tsung *et al.*** (The Journal of Immunology, 1998, vol. 160, pages 1369-1377) in view of **Pinedo *et al.*** (The Oncologist, 2000, vol. 5, pages 497-500) is **withdrawn** in light of Applicant's amendments and arguments.

Firstly, Applicants have amended the claims to recite administration of 1-methyl-D-tryptophan. WO '764 teaches administration of the racemic mixture of 1-methyl-DL-tryptophan and do not provide an explicit or inherent teaching or suggestion to administer the individual isomers. Secondly, even if it could be argued that the individual isomers are obvious over WO '764, the prior art teaches that 1-methyl-*L*-tryptophan is the substantially more potent inhibitor of indoleamine-2,3-dioxygenase (see Peterson et al. (Med. Chem. Res., 1994, vol., 3, pages 531-534). As such, the prior art teaches away from selecting 1-methyl-D-tryptophan for use as an inhibitor of indoleamine-2,3-dioxygenase in the cancer treatment methods disclosed in WO '764. Applicants have unexpectedly found that 1-methyl-D-tryptophan is more effective than the L

isomer at reversing IDO-mediated suppression and more effective than the racemic mixture is delaying tumor growth.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

U.S. Non-Provisional Application No. 10/780,150

Claims 1, 2, 4, 13, 30-34, and 44-69 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 6-7, 10, 17-18, and 97-132 of copending Application No. 10/780,150. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass the subject matter claimed in the '150 patent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant requests that this rejection be held in abeyance until the indication of otherwise allowable subject matter. As no allowable subject matter has been indicated in this Office Action, the rejection is maintained.

Allowable Subject Matter

Favorable consideration would be given to claims limited to the treatment of cancer comprising administering 1-methyl-D-tryptophan and cyclophosphamide.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES D. ANDERSON whose telephone number is (571)272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James D Anderson/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614